

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

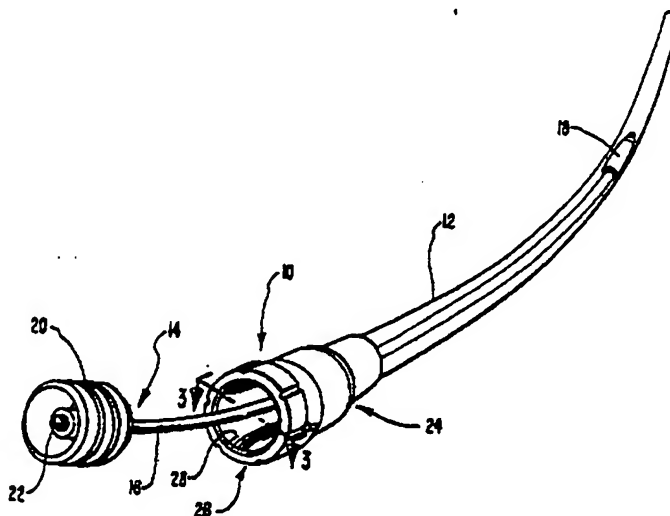




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification 5 :</b>  <b>A61M 5/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 92/11880</b>  <b>(43) International Publication Date:</b> <b>23 July 1992 (23.07.92)</b>
<b>(21) International Application Number:</b> PCT/US91/09699 <b>(22) International Filing Date:</b> 23 December 1991 (23.12.91) <b>(30) Priority data:</b> 633,975                      26 December 1990 (26.12.90) US <b>(71) Applicant:</b> CARDIOPULMONICS, INC. [US/US]; 5060 West Amelia Earhart Drive, Salt Lake City, UT 84116 (US). <b>(72) Inventors:</b> BERRY, Gaylord, L. ; 3020 East 3135 South, Salt Lake City, UT 84109 (US). KERBY, Lynn ; 1623 Casper Road, Draper, UT 84020 (US). <b>(74) Agents:</b> NYDEGGER, Rick, D. et al.; Workman, Nydegger & Jensen, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).		<b>(81) Designated States:</b> AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent).  <b>Published</b> <i>With international search report.</i> <i>With amended claims.</i>

**(54) Title:** ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE



**(57) Abstract**

A catheter valve (10) which can be used to effect selective closure of a catheter lumen in order to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body. The apparatus has a valve body with a hub (24) which is joined to the catheter, and a rotatable cap (26) which is joined to the hub (24). An elastomeric sleeve (38) is positioned in an opening (28) through the interior of the valve body. One end of the elastomeric sleeve (38) is joined to the rotatable cap (26) while the other end of the elastomeric sleeve (38) is joined to the hub (24). When the cap (26) is rotated in one direction to a first position, the circular opening (28) of the sleeve (38) is fully opened. When the cap (26) is rotated in the opposite direction to a second position, the elastomeric sleeve (38) is twisted intermediate the two ends so as to ultimately effect closure of the circular opening (28).

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Togo
DE	Germany	MC	Monaco	TC	Togo
DK	Denmark			US	United States of America

## ROTATABLY ACTUATED CONSTRICTING CATHETER VALVE

BACKGROUND1. Field of the Invention

5 The present invention relates to an apparatus for a catheter valve which can be used to limit or prevent the loss of body fluid from a patient's body when the catheter is introduced into the patient's body, or which can be used to otherwise control the injection or removal of fluids  
10 through the catheter.

2. Technological Background

15 There are many types of medical devices which must be inserted into a patient's body, such as tubes, catheters, needles, introducer sheathes and the like. As used herein, the term "catheter" is intended to embrace within its scope any devices through which fluids are intended to be injected into a patient's body or through which there is the potential for removal or loss of body fluid from the  
20 patient's body, including by way of example but not limitation, tubes, catheters, needles, or introducer sheathes through which catheters, needles or other medical devices can be introduced into a patient's body.

25 When using such catheter-type devices, it is typically necessary or desirable to either control the injection of fluids into the patient's body or to control, limit or prevent fluids from escaping through the lumen of the catheter-type device. To this end, there are many types of clamping or valving apparatus which have been devised. For example, there clamps or hemostats which can be placed on  
30 the outside and used to open or close tubes or catheters by pinching or collapsing the walls, thereby controlling fluid flow through the tube or catheter either into or out of the patient's body. These types of exterior clamps or hemostats are typically intended to maintain such tubes or  
35

1 catheters either fully open or fully closed. However,  
there are some circumstances in which it would be  
desireable to effect only partial closure of the lumen of  
the tube or catheter to permit reduced fluid flow. There  
5 are other types of circumstances where constriction of the  
lumen of such a tube or catheter must be effected in a  
manner so as to prevent loss of blood or other body fluid  
as another medical device is introduced through the tube or  
catheter into the patient's body.

10 It would be highly advantageous to have a valve which  
is capable of being used for any or all such types of fluid  
control through a catheter-type device.

#### BRIEF SUMMARY OF THE INVENTION

15 The present invention is directed to a novel apparatus  
for a catheter valve which can be used to effect selective  
closure of a catheter lumen in order to control fluid flow  
through the catheter lumen once the catheter is inserted  
into a patient's body. In a preferred embodiment of the  
20 invention, the valve body has a hub which is joined to a  
catheter-type device and a rotatable cap which is joined to  
the hub. An elastomeric sleeve is positioned in an opening  
through the interior of the valve body and one end of the  
elastomeric sleeve is joined to the rotatable cap while the  
25 other end of the elastomeric sleeve is joined to the hub.  
When the cap is rotated in one direction to a first  
position, the circular opening of the sleeve is fully  
opened. When the cap is rotated in the opposite direction  
to a second position, the elastomeric sleeve is twisted  
30 intermediate the two ends so as to ultimately effect  
closure of the circular opening of the sleeve when the cap  
is rotated to the second position. Due to the elastomeric  
properties of the sleeve, the circular opening of the  
elastomeric sleeve tends to be uniformly constricted as the  
35 cap is rotated to effect closure. The catheter valve of

1 the present invention can be operated to effect full  
opening or full closure of the circular opening through the  
valve body and can also be operated to effect variable  
constriction of the circular opening or to engage the  
3 circumference of a tube or other medical device inserted  
through the circular opening so as to prevent fluid flow  
from passage around the circumference of the medical  
device.

Various advantages of the invention will be apparent  
10 from the drawings, description and claims which follow, or  
may be learned by the practice of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described with additional detail  
15 and specificity through the use of the accompanying  
drawings which are briefly summarized below. The drawings  
and accompanying detailed description depict the presently  
preferred embodiment and presently understood best mode of  
practicing the invention but are not otherwise to be  
20 considered as limiting of the invention's scope, which is  
set forth in the claims and which are intended to embrace  
within their scope equivalent instrumentalities or  
combinations.

In the drawings, Figure 1 is a perspective illustration  
25 showing the valve of the present invention as used with a  
catheter-type device, as for example an introducer sheath,  
with an obturator that is inserted into the introducer  
sheath. In Figure 1 the catheter valve of the present  
invention is shown with the valve in a fully open position.

30 Figure 2 is a perspective illustration showing the  
catheter valve of the present invention rotated to effect  
closure of the circular opening through the valve body so  
as to prevent fluid from flowing through the valve body  
around the obturator.

1        Figure 3 is an enlarged cross-sectional view taken  
along line 3-3 of Figure 1.

Figure 4 is an enlarged cross-sectional view taken  
along line 4-4 of Figure 2.

3        Figure 5 is a cross-sectional view similar to that of  
Figure 4, but showing a smaller diameter obturator,  
catheter or tube and particularly illustrating the manner  
in which the circular opening of the catheter valve is  
uniformly and variably constricted to effect closure about  
10      the circumference of the device.

Figure 6A is an elevated side view of the catheter  
valve of the present invention which illustrates the  
rotatable valve cap at a first position wherein the  
circular opening of the valve body is fully open as  
15      illustrated in the corresponding elevated end view of  
Figure 6B.

Figures 6C and 6D are elevated side and end views, res-  
pectively, which particularly illustrate the rotatable  
valve cap rotated to an intermediate position so as to  
20      effect partial closure of the circular opening.

Figures 6E and 6F are elevated side and end views, res-  
pectively, which particularly illustrate the rotatable  
valve cap rotated to a second position to effect full  
closure of the circular opening through the valve body.

25

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Reference is now made to the drawings wherein like  
parts are designated with like numerals throughout.

Referring first to Figure 1, the catheter valve of the  
30      present invention is generally designated at 10. For  
purposes of illustration only, the valve 10 is illustrated  
as being coupled at one end of an introducer sheath 12. In  
the case of the particular introducer sheath 12 which is  
illustrated in Figure 1, the sheath 12 is designed  
35      particularly for insertion into the right jugular vein of



1 a patient in order to provide access to the patient's vena  
cava for purposes of introducing an in vivo blood  
oxygenation device. Also illustrated in connection with  
the introducer sheath 12 is an obturator which is generally  
5 designated at 14 and which comprises a rod-like elongated  
member 16 with a tip 18 connected thereto at one end (the  
distal end) and a gripping means 20 connected thereto at  
the other end (the proximal end). The obturator 14 adds  
stability to the sheath 10 and provides a blunt, atraumatic  
10 tip 18 to facilitate the insertion of the sheath 12 into a  
patient's venous system. Obturator 14 is also typically  
provided with a small diameter bore 22 that runs through  
the length of the elongated member 16 and through which a  
guide wire (not shown) may be threaded and which can be  
15 later used to aid in guiding the entry and positioning of  
a medical device such as an in vivo blood oxygenation  
device.

It should be understood that the sheath 12 and  
obturator 14 have been illustrated merely to show a typical  
20 application for which the valve of the present invention  
can be advantageously utilized, but is not otherwise  
intended to be limiting of the scope of the invention. The  
valve 10 may be advantageously used with any one of a  
variety of different types of tubes for administration of  
25 parenteral fluids, catheters for insertion into the  
arterial, venous or other parts of a patient's body or  
could be used in connection with various types of needles  
or other introducer sheath apparatus. Thus, as noted  
above, the valve of the present invention is intended to be  
30 used in connection with any such catheter-type device  
through which it is necessary or desirable to control,  
limit or prevent infusion or withdrawal of any type of  
fluids into or out of a patient.

With further reference to Figure 1, in the presently  
35 preferred embodiment of the invention as illustrated in the

1 drawings, the valve comprises a means for defining a valve  
body with an opening therethrough which communicates with  
the interior lumen of the sheath or catheter-type device to  
which it is connected. In the preferred embodiment, the  
5 means for defining the valve body is comprised of a hub  
means generally designated at 24 for joining the valve body  
to the elongated sheath 12 and is also comprised of a cap  
means as generally designated at 26 for rotatably joining  
said hub means. A circular opening 28 is provided through  
10 the interior of the valve body so as to provide fluid flow  
through the interior of the valve body. The circular  
opening 28 is shown in greater detail in Figure 3.

With further reference to Figure 3, in the presently  
preferred embodiment of the invention as illustrated, the  
15 hub means 24 is comprised of an outer cylindrical sleeve  
clamp 30 and an inner cylindrical sleeve clamp 32.  
Similarly, the rotatable cap means 26 is also comprised of  
an outer cylindrical sleeve clamp 34 and an inner  
cylindrical sleeve clamp 36. In a further aspect of the  
20 invention, the valve is comprised of a means for  
constricting the circular opening 28 through the valve body  
as the cap means 26 is rotated relative to the hub means 24  
such that when the cap means 26 is rotated to a first  
position the means for constricting does not obstruct the  
25 circular opening 28, and when the cap means 26 is rotated  
in an opposite direction to a second position, the means  
for constricting effects closure of the circular opening  
28.

In the presently preferred embodiment, as shown best in  
30 Figures 2-4 taken together, the means for constricting the  
circular opening of the valve body is comprised of an  
elongated, cylindrical elastomeric sleeve 38. Sleeve 38  
has one end 42 which is clamped and held firmly between the  
outer and inner cylindrical sleeve clamps 34 and 36 of  
rotatable cap means 26, whereas the other end 44 of the  
35

1 elastomeric sleeve 38 is firmly clamped and held between  
the outer and inner cylindrical sleeve clamps 30 and 32 of  
the hub means 24. Accordingly, when the cap means 26,  
including the outer and inner cylindrical sleeve clamps 34  
5 and 36 are rotated while the outer and inner cylindrical  
sleeve clamps 30 and 32 of the hub means 24 are held  
stationary, the elastomeric sleeve 38 is twisted  
intermediate the two ends 42 and 44 of sleeve 38 so as to  
effect closure of the opening 28 which is otherwise  
10 provided through the sleeve 38. Thus, as shown best in  
Figures 2 and 4, the elastomeric sleeve 38 will be  
collapsed upon the elongated member 16 of the obturator to  
provide a fluid-tight seal thereby preventing any fluid  
from flowing through the opening 28 in the space around the  
15 elongated member 16 of the obturator. In the alternative,  
if an obturator or other tube or catheter-type device is  
not inserted through the circular opening 28 of the valve  
body, the elastomeric sleeve 38 can be completely collapsed  
to effect full closure as illustrated, for example, in the  
20 elevated end view of Figure 6F.

With continued reference to the cross-sectional views  
of Figures 3 and 4, the outer cylindrical sleeve clamp 34  
of the rotatable cap means 26 is provided with a square  
shoulder 46. The vertical edge of the square shoulder 46  
25 provides a supporting abutment for a circular rim 48 that  
is formed on the inner cylindrical sleeve clamp 36. A  
portion 50 of the inner cylindrical sleeve clamp 36 extends  
beneath the horizontal edge of the square shoulder 46 of  
outer cylindrical sleeve clamp 34. The end 42 of  
30 elastomeric sleeve is firmly clamped and held between the  
horizontal edge of shoulder 46 and the portion 50 of inner  
cylindrical sleeve clamp 36 that extends therebeneath.

The opposite end 44 of the elastomeric sleeve 38 is  
firmly held and clamped between a horizontal extension 52  
35 of the outer cylindrical sleeve clamp 30 and a lower

1 horizontal extension 54 of the inner cylindrical sleeve  
clamp 32 of the hub means 24. The inner cylindrical sleeve  
clamp 32 of the hub means 24 is also comprised of a square  
shoulder 56 and the vertical edge of the square shoulder 56  
3 provides a supporting abutment for the end of the  
horizontal extension member 52. The inner cylindrical  
sleeve clamp 32 also provides an upper horizontal extension  
member 58 which projects beneath an overhanging lip 60 on  
the outer cylindrical sleeve clamp 34 of the rotatable cap  
10 means 26. Further, the inner cylindrical sleeve clamp 36  
of the rotatable cap means 26 also has a horizontal support  
member 62 which provides a rotational bearing surface upon  
which the upper horizontal extension member 58 rests. The  
outer and inner cylindrical sleeve clamps 34 and 36 of the  
15 rotatable cap means 26 are firmly bonded or otherwise  
secured together so as to provide a unitary piece which  
rotates relative to the inner and outer cylindrical sleeve  
clamps 30 and 32 of the hub means 24.

Because of the rotatable bearing surface provided by  
20 the horizontal support member 62 which supports the  
horizontal extension member 58, the outer cylindrical  
sleeve clamp 34 can be grasped and rotated in either  
direction therefore rotating both the inner and outer  
cylindrical sleeve clamps 34 and 36 relative to the outer  
25 and inner sleeve clamps 30 and 32 of the hub means 24. The  
effect of this rotational movement will be to twist the  
elastomeric sleeve 38 such as illustrated at point 40  
thereby collapsing the elastomeric sleeve 38 at that point.  
In this manner, the elastomeric sleeve 38 will serve as a  
30 means for constricting the circular opening in an  
essentially uniform, variable fashion, as illustrated best  
in the elevated end views of Figures 6B, 6D and 6F.

In Figure 6B the elastomeric sleeve is not rotated so  
that the circular opening 28 is fully open. In Figure 6D  
35 the rotatable cap means has been partially rotated to

1 effect partial closure of the circular opening 28 by  
causing a partial collapse of the elastomeric sleeve 38 at  
point 40 due to the twisting effect of rotating one end of  
the sleeve 38 relative to the other. In Figure 6F full  
3 closure of the circular opening has been effected by  
completely rotating one end of the elastomeric sleeve 38  
relative to the other until the elastomeric sleeve has been  
completely twisted to a closed condition.

As will be further appreciated in reference to Figures  
10 2-5, the elastomeric sleeve 38 can also provide effective  
closure and fluid-tight seal against an obturator or other  
tube-like device which is inserted through the circular  
opening 28. In the case of Figures 2-4, the elongated rod-  
like member 16 of the obturator can be left free to slide  
15 in or out of the circular opening when the elastomeric  
sleeve 38 is in an open or partially closed condition, or  
alternatively the elastomeric sleeve 38 can be twisted to  
effect closure and to provide a fluid-tight seal against  
the elongated rod-like member 16 by the aforementioned  
20 rotational movement of the cap means 26 relative to the hub  
means 24. Figure 5 illustrates how a tube or rod of  
smaller diameter such as illustrated at 16A can also be  
effectively sealed within the circular opening 28 by  
twisting one end of the elastomeric sleeve 38 relative to  
25 the other.

With further reference to Figures 3 and 4, the outer  
cylindrical sleeve clamp 30 is tapered at portion 64 and  
terminates in a cylindrical inner collar 66. A cylindrical  
outer collar 68 fits over the inner collar 66 and is used  
30 to clamp the end of the sheath or other catheter-like  
device 12 between the two so as to join the hub means 24 to  
the sheath or catheter-like device 12.

The manner of operating the valve of the present  
invention is best understood in reference to Figures 6A-6F.  
35 As will be seen best in the elevated side views of Figures

6A, 6C and 6E, the outer cylindrical sleeve clamp 34 also serves as a cap which can be rotated relative to the hub of the valve. The rotatable cap has a lip 60 which extends partially around the circumference of the valve. At one end of the lip 60 there is a notch 72 provided which defines a first position for the rotatable cap. At the other end of the lip 60, as shown best in Figure 6E, there is a second notch 76 which is formed, which defines a second position of the rotatable cap. A post 70 (see also Figures 3 and 4) is anchored in the inner cylindrical sleeve clamp 32 of the hub means.

Post 70 in conjunction with the lip 60 serves as a stop means for limiting rotational movement of the rotatable cap in either direction of rotation. Accordingly, when the rotatable cap is rotated to the position shown in Figure 6A, the elastomeric sleeve 38 is fully open so as not to obstruct the circular opening 28 of the valve body. When the rotatable cap is partially rotated as shown in Figure 6C the elastomeric sleeve 38 will partially constrict as it begins to twist at the intermediate portion of its length. Thus, as shown in Figure 6D the circular opening 28 will be partially obstructed when the cap is rotated to the position of Figure 6C. When the rotatable cap is fully rotated in the opposite direction to the notch 76 so that the rotatable cap will be held in that position by the post 70, the elastomeric sleeve 38 will effect full closure of the circular opening 28, as shown in Figure 6F. As will be further appreciated from Figures 6A, 6C and 6E taken together, the rotatable cap has a portion of its length shortened as illustrated at 74 so as to permit rotation of the cap relative to the post 70 which provides a stop for engaging the notched positions 72 or 76.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be

11

1 considered in all respects only as illustrative and not  
restrictive. The scope of the invention is, therefore,  
indicated by the appended claims rather than by the  
foregoing description. All changes which come within the  
3 meaning and range of equivalency of the claims are to be  
embraced within their scope.

10

15

20

25

30

35

## CLAIMS:

1. A valve for effecting selective closure of a catheter lumen to control fluid flow through the catheter lumen once the catheter is inserted into a patient's body, the valve comprising:

means for defining a valve body with an opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and

means for constricting said opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for constricting does not obstruct said opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said opening.

2. A valve as defined in claim 1 wherein said hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

3. A valve as defined in claim 2 wherein said cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a



1 second position, said elastomeric sleeve is twisted to  
effect closure of the sleeve.

5 5. A valve as defined in claim 2 wherein said hub  
means further comprises a cylindrical catheter clamp.

6. A reflux valve as defined in claims 1 and 2  
further comprising stop means for limiting rotation of said  
cap means relative to said hub means so as to stop said cap  
10 means at said first position when rotated in one direction,  
and so as to stop said cap means at said second position  
when rotated in an opposite direction.

7. A reflux valve as defined in claim 6 wherein said  
15 stop means comprises:

a post anchored in the inner cylindrical sleeve  
clamp of said hub means; and

a lip extending around a portion of the  
circumference of said outer cylindrical sleeve clamp of  
20 said cap means.

8. A valve for controlling fluid flow through a  
catheter connected to said valve when the catheter is  
inserted into a blood vessel, said valve comprising:

25 a valve body comprised of a hub means for joining  
said valve to said catheter and a cap means for  
rotatably joining to said hub means, said hub means and  
said cap means each comprising a means for clamping an  
end of an elastomeric sleeve; and

30 a cylindrical, elastomeric sleeve having one end  
clamped to said hub means, and having another end  
clamped to said cap means, such that when said cap  
means is rotated relative to said hub means to a first  
position, said elastomeric sleeve is untwisted and  
open, and when said cap means is rotated relative to  
35

2       said hub means to a second position, said elastomeric  
sleeve is twisted to effect closure of the sleeve.

3       9. A valve as defined in claim 8 further comprising  
4 stop means for limiting rotation of said cap means relative  
to said hub means so as to stop said cap means at said  
first position when rotated in one direction, and so as to  
stop said cap means at said second position when rotated in  
an opposite direction.

10

10. A valve as defined in claim 9 wherein said stop  
means comprises:

a post anchored in the inner cylindrical sleeve  
clamp of said hub means; and

15       a lip extending around a portion of the  
circumference of said outer cylindrical sleeve clamp of  
said cap means.

20       11. A valve as defined in claim 10 wherein said hub  
means further comprises a cylindrical catheter clamp.

25       12. A valve as defined in claim 8 wherein each said  
means for clamping an end of said elastomeric sleeve  
comprises an outer cylindrical sleeve clamp and an inner  
cylindrical sleeve clamp.

30       13. A valve for effecting selective closure of a  
catheter lumen to control fluid flow through the catheter  
lumen once the catheter is inserted into a patient's body,  
the valve comprising:

means for defining a valve body with an opening  
therethrough which communicates with said catheter  
lumen, said means for defining said valve body  
comprising hub means for joining said valve body to

35

1        said catheter, and cap means for rotatably joining to  
      said hub means;

      means for constricting said opening of the valve  
body as said cap means is rotated relative to said hub  
5        means, such that when said cap means is rotated to a  
first position said means for constricting does not  
obstruct said opening, and when said valve body is  
rotated to a second position, said means for  
constricting effects closure of said opening; and

10       stop means for limiting rotation of said cap means  
relative to said hub means so as to stop said cap means  
at said first position when the cap means is rotated in  
one direction, and so as to stop said cap means at said  
second position when the cap means is rotated in an  
15       opposite direction.

      14. A valve as defined in claim 13 wherein said hub  
means comprises an outer cylindrical sleeve clamp and an  
inner cylindrical sleeve clamp.

20

      15. A valve as defined in claim 14 wherein said cap  
means comprises an outer cylindrical sleeve clamp and an  
inner cylindrical sleeve clamp.

25       16. A valve as defined in claim 15 wherein said means  
for constricting said opening comprises a cylindrical,  
elastomeric sleeve having one end clamped between the inner  
and outer sleeve clamps of said hub means, and having  
another end clamped between the inner and outer sleeve  
30       clamps of said cap means, such that when said cap means is  
rotated relative to said hub means to a first position,  
said elastomeric sleeve is untwisted and open, and when  
said cap means is rotated relative to said hub means to a  
second position, said elastomeric sleeve is twisted to  
35       effect closure of the sleeve.

17. A valve as defined in claim 16 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

19. A valve for effecting selective closure of a catheter lumen to prevent escape of body fluid through the catheter lumen when a tube is inserted through the catheter lumen and the catheter is inserted into a patient's body, the valve comprising:

means for defining a valve body with a circular opening therethrough which communicates with said catheter lumen, said tube extending through the circular opening into the lumen of said catheter, and said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means; and

means for variably constricting said circular opening of the valve body as said cap means is rotated relative to said hub means, such that when said cap means is rotated to a first position said means for variably constricting said circular opening does not obstruct said circular opening so that said tube is freely slidable through said circular opening and the lumen of said catheter, and such that when said valve body is rotated to a second position said means for variably constricting said circular opening uniformly closes around said tube and frictionally engages said

1 tube to prevent escape of body fluid through said lumen  
and around said tube through the circular opening.

20. A valve as defined in claim 19 further comprising  
5 stop means for limiting rotation of said cap means relative  
to said hub means so as to stop said cap means at said  
first position when rotated in one direction, and so as to  
stop said cap means at said second position when rotated in  
an opposite direction.

10

21. A valve as defined in claim 20 wherein said stop  
means comprises:

a post anchored in the inner cylindrical sleeve  
clamp of said hub means; and

15 a lip extending around a portion of the  
circumference of said outer cylindrical sleeve clamp of  
said cap means.

22. A valve as defined in claim 19 wherein said hub  
20 means comprises an outer cylindrical sleeve clamp and an  
inner cylindrical sleeve clamp.

23. A valve as defined in claim 22 wherein said cap  
means comprises an outer cylindrical sleeve clamp and an  
25 inner cylindrical sleeve clamp.

24. A valve as defined in claim 23 wherein said means  
for constricting said opening comprises a cylindrical,  
elastomeric sleeve having one end clamped between the inner  
and outer sleeve clamps of said hub means, and having  
30 another end clamped between the inner and outer sleeve  
clamps of said cap means, such that when said cap means is  
rotated relative to said hub means to a first position,  
said elastomeric sleeve is untwisted and open, and when  
35 said cap means is rotated relative to said hub means to a

18

1 second position, said elastic sleeve is twisted to  
effect closure of the sleeve.

5

10

15

20

25

30

35

## AMENDED CLAIMS

[received by the International Bureau on 1 June 1992 (01.06.92);  
original claims 1-24 replaced by amended claims 1-24  
(8 pages)]

1  
1. A valve for effecting selective closure of a catheter lumen to control fluid flow through said catheter lumen once a catheter is inserted into a patient's body, said valve comprising:

5 means for defining a valve body with an inside opening therethrough which communicates with said catheter lumen, said means for defining said valve body comprising hub means for joining said valve body to said catheter, and cap means for rotatably joining to said hub means, and the hub means and cap means each comprising a clamping means; and

10 means for constricting said inside opening of said valve body as said cap means is rotated relative to said hub means and said means for constricting having one end wrapped around and clamped by the clamping means of the hub means, and having another end wrapped around and clamped by the clamping means of the cap means, so as to provide an unobstructed lining along said inside opening of said valve body, such that when said cap means is rotated to a first position said means for constricting does not obstruct said inside opening, and when said cap means is rotated to a second position, said means for constricting effects closure of said inside opening of said valve body.

15 2. A valve as defined in claim 1 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

20 3. A valve as defined in claim 2 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

1

4. A valve as defined in claim 3 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having  
5 another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when  
10 said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

15

5. A valve as defined in claim 2 wherein said hub means further comprises a cylindrical catheter clamp.

20

6. A reflux valve as defined in claims 1 or 2 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

25

7. A reflux valve as defined in claim 6 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.  
30

35

8. A valve for controlling fluid flow through a catheter connected to said valve when said catheter is inserted into a blood vessel, said valve comprising:

a valve body having an inside opening, said valve body comprised of a hub means for joining said valve



1 to said catheter and a cap means for rotatably joining  
to said hub means, said hub means and said cap means  
each comprising a means for clamping an end of a  
5 cylindrical elastomeric sleeve, said cylindrical,  
elastomeric sleeve having one end wrapped around one  
of said clamping means and clamped to said hub means,  
and having another end wrapped around the other said  
clamping means clamped to said cap means, such that  
10 when said cap means is rotated relative to said hub  
means to a first position, said cylindrical  
elastomeric sleeve is untwisted and open, and provides  
an uninterrupted seamless lining along said inside  
opening of said valve body, and when said cap means is  
15 rotated relative to said hub means to a second  
position, said cylindrical elastomeric sleeve is  
twisted to effect closure of said opening of said  
valve body.

20 9. A valve as defined in claim 8 further comprising  
stop means for limiting rotation of said cap means relative  
to said hub means so as to stop said cap means at said  
first position when rotated in one direction, and so as to  
stop said cap means at said second position when rotated in  
25 an opposite direction.

10. A valve as defined in claim 9 wherein said stop  
means comprises:  
a post anchored in the inner cylindrical sleeve  
30 clamp of said hub means; and  
a lip extending around a portion of the  
circumference of said outer cylindrical sleeve clamp  
of said cap means.

11. A valve as defined in claim 10 wherein said hub  
35 means further comprises a cylindrical catheter clamp.

1           12. A valve as defined in claim 8 wherein each said  
means for clamping an end of said elastomeric sleeve  
comprises an outer cylindrical sleeve clamp and an inner  
5           cylindrical sleeve clamp.

10           13. A valve for effecting selective closure of a  
catheter lumen to control fluid flow through said catheter  
lumen once a catheter has been inserted into a patient's  
body, said valve comprising:

15               means for defining a valve body with an inside  
opening therethrough which communicates with said  
catheter lumen, said means for defining said valve  
body comprises hub means for joining said valve body  
to said catheter lumen, and cap means for rotatably  
20           joining to said hub means said catheter lumen, and the  
hub means and cap means each comprising a clamping  
means;

25               means for constricting said opening of said valve  
body as said cap means is rotated relative to said hub  
means, such that when said cap means is rotated to a  
first position said means for constricting does not  
obstruct said opening and said means for constricting  
having one end wrapped around and clamped by the  
30           clamping means of the hub means, and having another  
end wrapped around and clamped by the clamping means  
of the cap means, so as to provide an unobstructed  
lining along said inside opening of said valve body,  
and when said valve body is rotated to a second  
position, said means for constricting effects closure  
of said opening of said valve body; and

35               stop means for limiting rotation of said cap  
means relative to said hub means so as to stop said  
cap means at said first position when said cap means  
is rotated in one direction, and so as to stop said

1

cap means at said second position when said cap means is rotated in an opposite direction.

5

14. A valve as defined in claim 13 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

10

15. A valve as defined in claim 14 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

15

20

16. A valve as defined in claim 15 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

25

17. A valve as defined in claim 16 wherein said stop means comprises:

30

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

35

18. A valve as defined in claim 17 wherein said hub means further comprises a cylindrical catheter clamp.

1           19. A valve for effecting selective closure of a  
catheter lumen and about a tube inserted therethrough to  
prevent escape of body fluid through said catheter lumen  
5 when said catheter is inserted into a patient's body, said  
valve comprising:

means for defining a valve body with a circular  
opening through the inside of said valve body and  
which communicates with said catheter lumen, said  
10 means for defining said valve body comprising hub  
means for joining said valve body to said catheter  
lumen, and cap means for rotatably joining to said hub  
means, and the hub means and cap means each comprising  
a clamping means; and

15 means for variably constricting said circular  
opening of said valve body as said cap means is  
rotated relative to said hub means, said means for  
variably constricting having one end wrapped around  
and clamped by the clamping means of the hub means,  
20 and having another end wrapped around and clamped by  
the clamping means of the cap means so as to provide  
an unobstructed lining along said opening along the  
inside of said valve body, such that when said cap  
means is rotated to a first position said means for  
25 variably constricting said circular opening seamlessly  
lines the inside of said valve body but does not  
obstruct said circular opening so that said tube is  
freely slidable through said circular opening and the  
lumen of said catheter, and such that when said valve  
30 body is rotated to a second position said means for  
variably constricting said circular opening uniformly  
closes around said tube and frictionally engages said  
tube to prevent escape of body fluid through said  
catheter lumen and around said tube through said  
35 circular opening of said valve body.

1

20. A valve as defined in claim 19 further comprising stop means for limiting rotation of said cap means relative to said hub means so as to stop said cap means at said first position when rotated in one direction, and so as to stop said cap means at said second position when rotated in an opposite direction.

5

10

21. A valve as defined in claim 20 wherein said stop means comprises:

a post anchored in the inner cylindrical sleeve clamp of said hub means; and

a lip extending around a portion of the circumference of said outer cylindrical sleeve clamp of said cap means.

15

20

22. A valve as defined in claim 19 wherein said clamping means of the hub means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

25

23. A valve as defined in claim 22 wherein said clamping means of the cap means comprises an outer cylindrical sleeve clamp and an inner cylindrical sleeve clamp.

30

24. A valve as defined in claim 23 wherein said means for constricting said opening comprises a cylindrical, elastomeric sleeve having one end clamped between the inner and outer sleeve clamps of said hub means, and having another end clamped between the inner and outer sleeve clamps of said cap means, such that when said cap means is rotated relative to said hub means to a first position, said elastomeric sleeve is untwisted and open, and when said cap means is rotated relative to said hub means to a

35

1

second position, said elastomeric sleeve is twisted to effect closure of the sleeve.

5

10

15

20

25

30

35

1/4

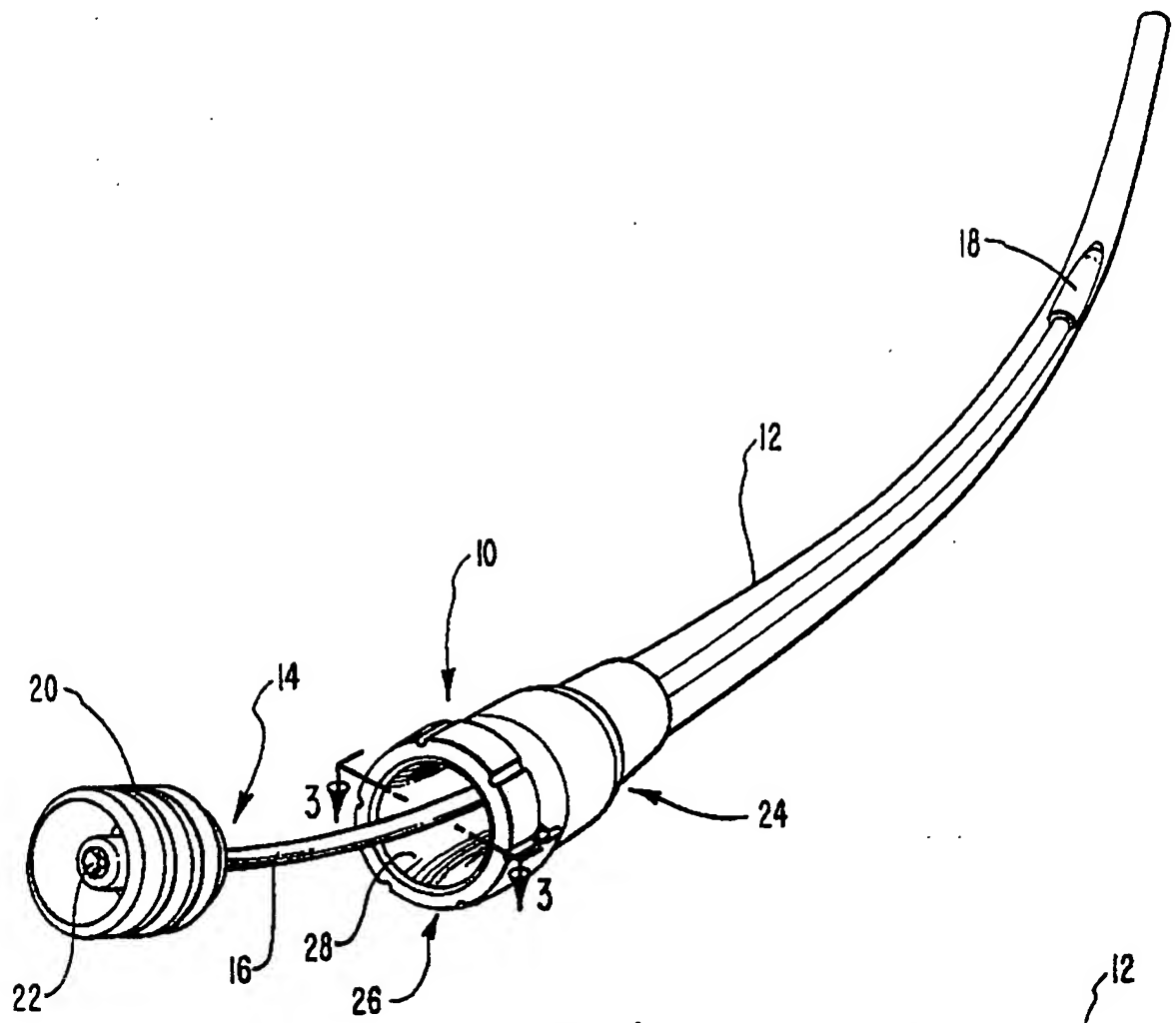


FIG. 1

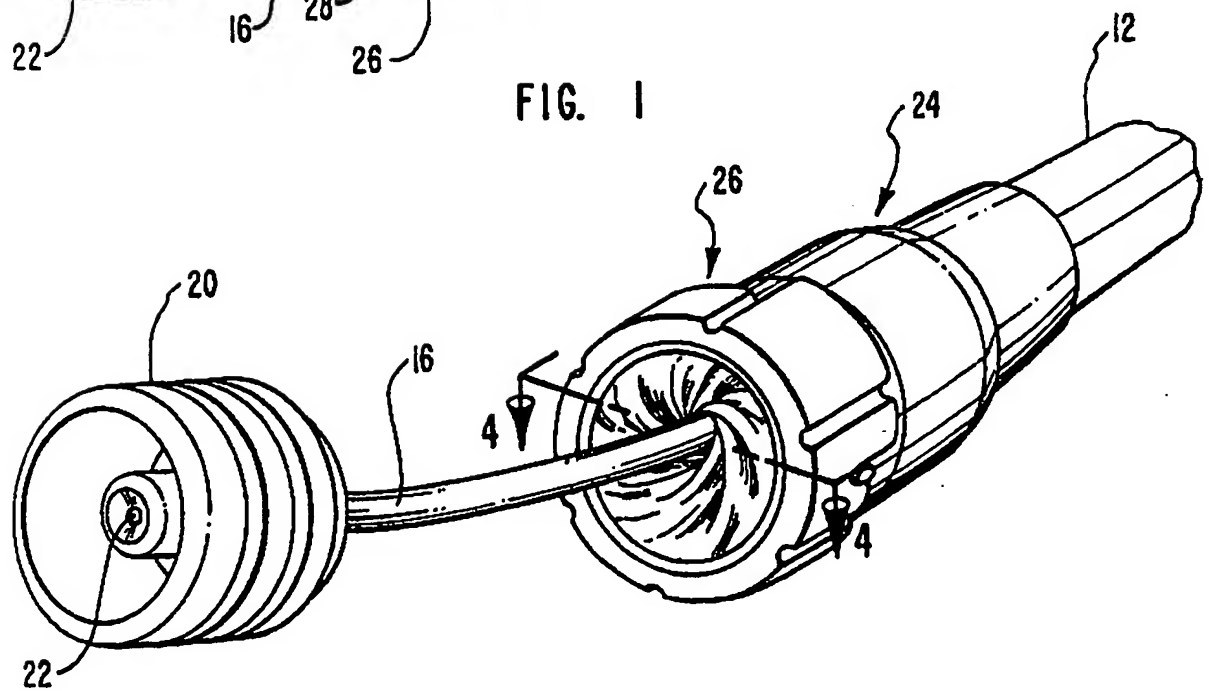


FIG. 2

2/4

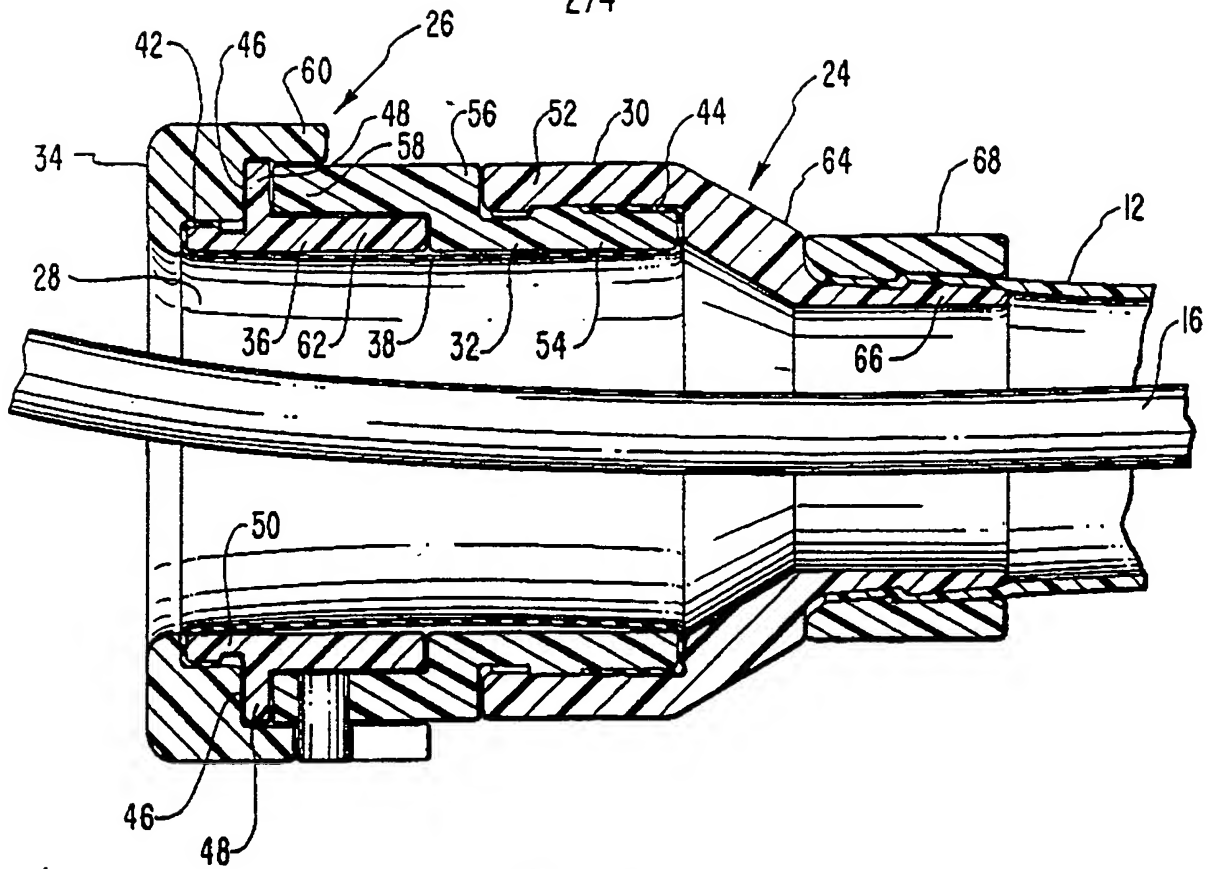


FIG. 3

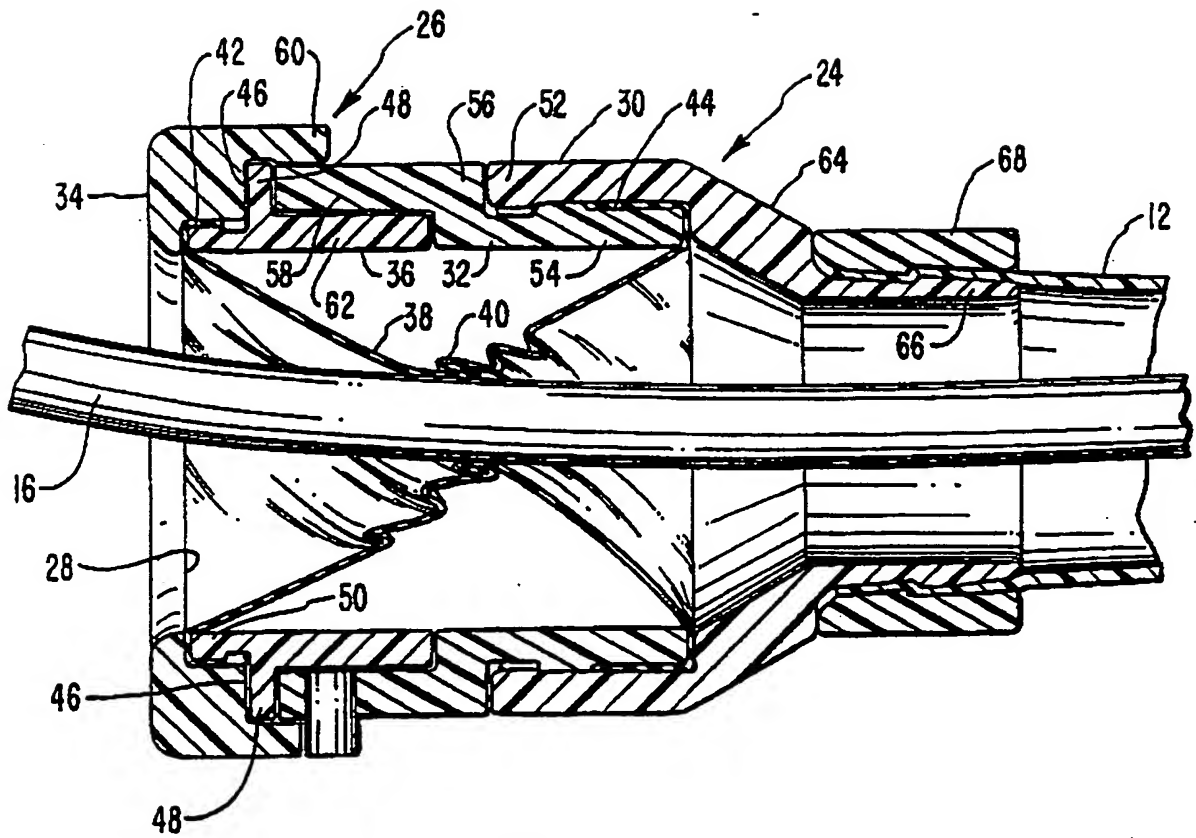


FIG. 4



3/4

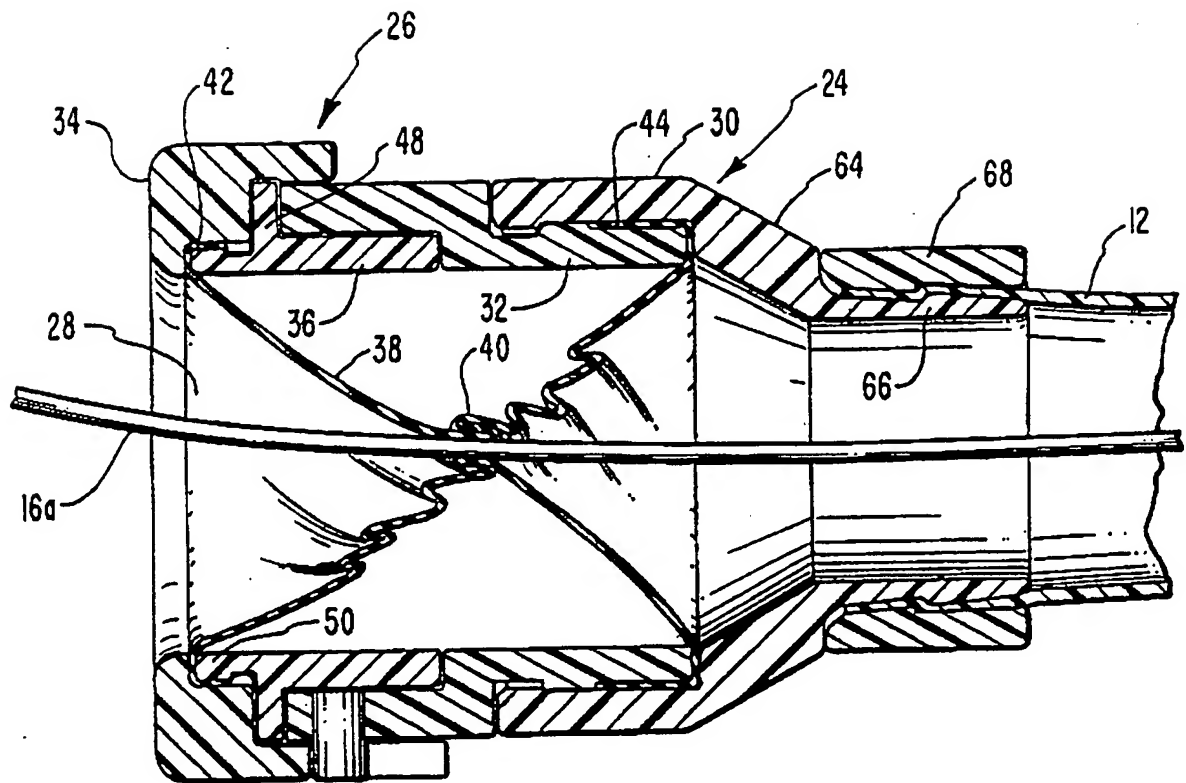


FIG. 5

4/4

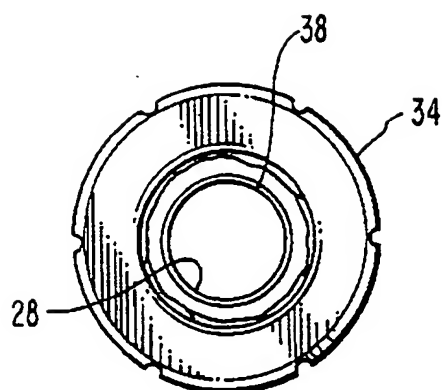


FIG. 6B

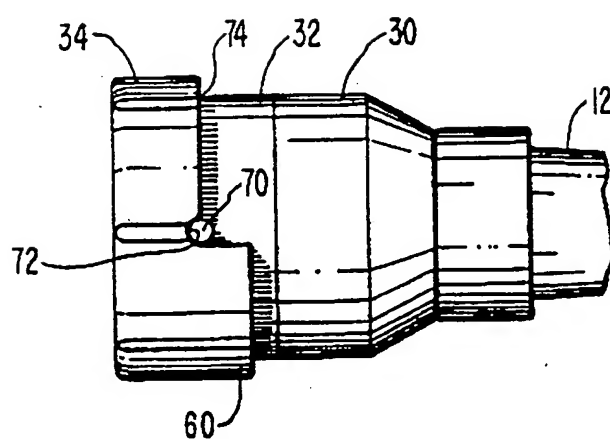


FIG. 6A

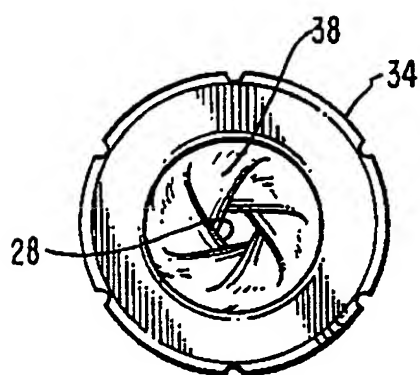


FIG. 6D

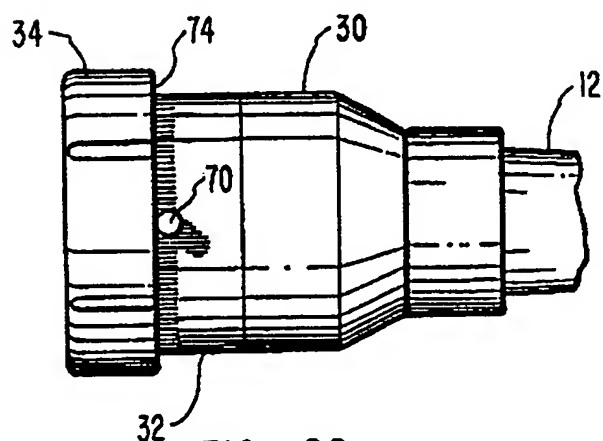


FIG. 6C

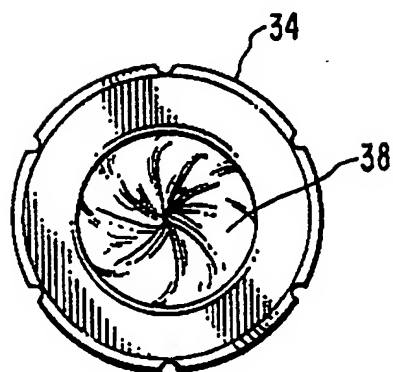


FIG. 6F

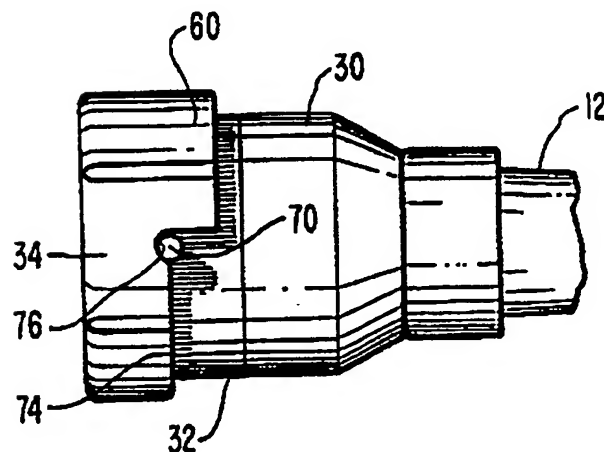


FIG. 6E

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/09699

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): A61M 5/00 U.S. CL: 604/248		
<b>II. FIELDS SEARCHED</b> Minimum Documentation Searched 7		
Classification System  U. S.	Classification Symbols  604/248,256,167,246,169,164,32,237,236,264	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT *</b>		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages d	Relevant to Claim No. 1-3
X Y	US, A, 4,540,411 (BODICKY) 10 SEPTEMBER 1985 See the entire document.	1-5,8,12,19 22-24 6,7,9-11,13-18, 20,21
Y	US, A, 3,185,179 (HARAJTUNEIAN) 25 MAY 1965 See Figures 4 and 5.	2-7,9-18,20-24
X Y	US, A, 4,580,573 (QUINN) 08 APRIL 1986 See entire document.	1, 8, 19 2-7,9-18,20-24
A	US, A, 4,314,555 (SAGAE) 09 FEBRUARY 1982 See entire document.	1-24
A	US, A, 4,978,341 (NIEDERHAUSER) 18 DECEMBER 1990 See entire document.	1-24
A	US, A, 2,844,351 (SMITH) 22 JULY 1958 See entire document.	1-24
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: 10</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search  28 FEBRUARY 1992  International Searching Authority ISA/US	Date of Mailing of this International Search Report 30 MAR 1992  Signature of Authorized Officer: <i>Jeffrey A. Smith</i> JEFFREY A. SMITH	

THIS PAGE BLANK (USPTO)